



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2022-0417; FRL-10108-01-OCSP]

Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) hereby announces its intent to cancel the registrations of three pesticide products containing the insecticide chlorpyrifos due to the Agency's revocation of all tolerances for chlorpyrifos. This document identifies the products at issue, summarizes EPA's basis for this Notice of Intent to Cancel (NOIC), and explains how adversely affected persons may request a hearing and the consequences of requesting or failing to request such a hearing.

DATES: The affected registrant must request a hearing within 30 days from the date that the affected registrant receives EPA's NOIC, or on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], whichever occurs later. Other adversely affected parties must request a hearing on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Please see unit VII. for specific instructions.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA-HQ-OPP-2022-0417, is available online at <https://www.regulations.gov>. Additional instructions on visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings, 40 CFR part 164. Requests for hearing must be filed with the Hearing

Clerk in EPA's Office of Administrative Law Judges (OALJ), in conformance with the requirements of 40 CFR part 164. The OALJ uses different addresses depending on the delivery method. Please see unit VII. for specific instructions.

FOR FURTHER INFORMATION CONTACT: Elissa Reaves, Pesticide Re-Evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-0700; email address: *OPPChlorpyrifosInquiries@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

EPA is announcing its intent to cancel the registrations of three pesticide products containing the insecticide chlorpyrifos due to the revocation of all chlorpyrifos tolerances. Specifically, EPA intends to cancel each of the following pesticide products, which allow for use on food crops, listed in sequence by EPA registration number.

- EPA Reg. No. 93182-3 Chlorpyrifos Technical.
- EPA Reg. No. 93182-7 Pilot 4E Chlorpyrifos Agricultural Insecticide.
- EPA Reg. No. 93182-8 Pilot 15G Chlorpyrifos Agricultural Insecticide.

The following information is the address on record for Gharda, the registrant of the products listed in this unit and subject to this notice, and includes the company number which corresponds to the first part of the EPA registration number of the products:

- EPA Co. No. 93182 – Gharda Chemicals International, Inc., 4932 Crockers Lake Blvd., Suite 818, Sarasota, Florida 34238.

In addition, this document summarizes EPA's legal authority for the proposed cancellation (see unit II.); the revocation of tolerances for residues of chlorpyrifos on food commodities (see unit III.); the Agency's rationale for issuance of this NOIC (see unit IV.); the timing of the proposed cancellations, EPA's existing stocks determination, and the potential

scope of any final cancellation order (see unit V.); the results of the Agency's coordination with the U.S. Department of Agriculture (USDA) and the FIFRA Science Advisory Panel (SAP) (see unit VI.); and how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing (unit VII.).

B. What is the Agency's authority for this action?

The Agency's authority to cancel a pesticide that does not comply with the provisions of FIFRA is contained in FIFRA section 6(b), 7 U.S.C. 136d(b).

C. Who may be affected by this action?

This announcement will directly affect the pesticide registrant listed in unit I.A., supplemental distributors, and others who may distribute, sell, or use the products listed in unit I.A. This announcement may also be of particular interest to a wide range of stakeholders including environmental, human health, farmworker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. EPA believes the stakeholders described above encompass those likely to be affected; however, more remote interests may also be affected, and the Agency has not attempted to describe all specific entities that may be affected by this action.

II. Legal Authority

With minor exceptions not at issue here, as provided in FIFRA section 3(a), a pesticide product may not be lawfully sold or distributed in the United States unless and until the product is registered by EPA. 7 U.S.C. 136a(a). A pesticide registration is a license allowing a pesticide product to be sold and distributed and includes a label with use instructions that delineates the specific uses for which the pesticide may be used, including precautions and other terms and conditions established by EPA when it grants the registration.

As a general matter, in order to obtain or maintain a registration for a pesticide under FIFRA, an applicant or registrant must demonstrate that the pesticide satisfies the statutory standard for registration. 7 U.S.C. 136a(c)(5). That standard requires, among other things, that

the pesticide perform its intended function without causing “unreasonable adverse effects on the environment.” *Id.* The term “unreasonable adverse effects on the environment” is defined under FIFRA section 2(bb) as including two parts: (1) “[A]ny unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide” and (2) “[A] human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21.” 7 U.S.C. 136(bb). It is under the second part of the definition that the FIFRA registration standard incorporates the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, safety standard.

EPA establishes, modifies, or revokes tolerances for pesticide residues under FFDCA section 408. 21 U.S.C. 346a. A “tolerance” represents the maximum level for residues of a pesticide legally allowed in or on raw agricultural commodities and processed food. Under the FFDCA, “any pesticide chemical residues in or on a food shall be deemed unsafe,” unless a tolerance or exemption for such residues “is in effect”. 21 U.S.C. 346a(a)(1). In other words, without a tolerance or an exemption from the requirement of a tolerance, pesticide residues in or on food are considered unsafe, as a matter of law. The consequence of having pesticide residues in or on food that are not covered by a tolerance, or an exemption is that the food containing such residues is rendered adulterated under the FFDCA. 21 U.S.C. 342(a)(2)(B). It is a violation of the FFDCA to introduce adulterated food into interstate commerce. 21 U.S.C. 331(a).

Because the FIFRA registration standard incorporates the FFDCA safety standard, a pesticide that results in residues in or on food that are unsafe, which includes residues not covered by a tolerance or tolerance exemption, does not meet the FIFRA registration standard. EPA will not approve any application to register a pesticide with food uses that may reasonably be expected to result in pesticide residues on food without appropriate tolerances or exemptions in place, *see* 40 CFR 152.112(g), and registrations bearing labeling for food use must be modified or cancelled, pursuant to FIFRA section 6(b).

The burden of demonstrating that a pesticide product satisfies the statutory criteria for registration is at all times on the proponents of the initial or continued registration and continues as long as the registration is in effect. 40 CFR 164.80(b); *see also Industrial Union Dept. v. American Petroleum Institute*, 448 U.S. 607, 653 n.61 (1980); *Stearns Electric Paste v. EPA*, 461 F.2d 293 (7th Cir. 1972); *Environmental Defense Fund v. EPA*, 510 F.2d 1292, 1297 (D.C. Cir. 1975).

Under FIFRA section 6(b), the Agency may issue a notice of its intent to cancel a registration of a pesticide product whenever it appears either that “a pesticide or its labeling or other material required to be submitted does not comply with FIFRA, or when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.” 7 U.S.C. 136d(b). The cancellation proposed in the notice shall become final 30 days after publication of the notice, or the date the registrant receives the notice, whichever is later, unless the registrant makes the necessary corrections to the registrations, or a hearing is requested by a person adversely affected by the notice. If a hearing is requested by an adversely affected person, the final order concerning cancellation of the product is not issued until after an administrative hearing.

A cancellation hearing shall be conducted in accordance with the regulations establishing the procedures for hearings under FIFRA set forth at 40 CFR part 164. Under those regulations, the Agency has the burden of presenting an affirmative case for cancellation. 40 CFR 164.80(a). However, the ultimate burden of proof is on the proponent of the registration. 40 CFR 164.80(b); *Industrial Union Dept.*, 448 U.S. at 653, n. 61; *Stearns Electric Paste v. EPA*, 461 F.2d 293 (7th Cir. 1972). Once the Agency makes its *prima facie* case that a product’s continued use fails to meet the FIFRA standard for registration, the responsibility to demonstrate that the product meets the FIFRA standard is upon the proponents of continued registration. 40 CFR 164.80(b); *Dow v. Ruckelshaus*, 477 F.2d 1317, 1324 (8th Cir. 1973).

III. Revocation of Chlorpyrifos Tolerances

Chlorpyrifos is a broad-spectrum, chlorinated organophosphate insecticide that is registered for a wide variety of food and non-food uses. In September 2007, Pesticide Action Network North America and Natural Resources Defense Council filed a petition with EPA requesting revocation of all chlorpyrifos tolerances alleging that, among other things, the pesticide caused adverse neurodevelopmental effects in children at exposure levels below the Agency's regulatory standard (*i.e.*, 10% acetylcholinesterase inhibition). See Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos, available at <https://www.regulations.gov>, using document identification number EPA-HQ-OPP-2007-1005-0005. Following several years of proposed responses and litigation, EPA issued a final response to the petition on March 29, 2017. *See* 82 FR 16581, April 5, 2017 (FRL-9960-77). That response denied the many claims of the petition, including by concluding that, despite several years of study, the science addressing neurodevelopmental effects remained unresolved and that further evaluation of the science on this issue during the remaining time for completion of registration review was warranted. *See id.* at 16590. As permitted under the FFDCA, objections to EPA's denial were filed, and EPA responded to those objections on July 18, 2019. *See* 84 FR 35555, July 18, 2019 (FRL-9997-06). In its denial of those objections, rather than issuing a determination concerning the safety of chlorpyrifos, EPA denied the objections in part on the grounds that the data concerning neurodevelopmental toxicity were not sufficiently valid, complete, and reliable to meet the petitioners' burden. *See id.* at 35562. EPA's denial of the petition and denial of objections were subsequently challenged by several advocacy groups and states in the Ninth Circuit.

On April 29, 2021, the Ninth Circuit Court of Appeals ruled against EPA in litigation involving the question of whether the chlorpyrifos tolerances should be revoked. *See League of United Latin American Citizens et al., v. Regan*, 996 F.3d 673 (9th Cir. 2021) ("*LULAC*"). In that case, the Court concluded that EPA violated the FFDCA by not making a safety determination to support the retention of the chlorpyrifos tolerances, as required under the FFDCA. Consequently,

the Court ordered EPA to issue a final rule in which the Agency would either revoke the tolerances (if it could not make the requisite safety finding to leave tolerances in place) or modify the existing chlorpyrifos tolerances, provided that the Agency concurrently issued a safety determination supporting the modified tolerances. The Court imposed a tight deadline for EPA to issue the final rule and told EPA not to engage in further fact-finding or delay.

Specifically, the court said: “To be clear, however, this is not an open-ended remand or a remand for further factfinding. The EPA must act based upon the evidence and must immediately revoke or modify chlorpyrifos tolerances. For these reasons, the Court remands this matter to the EPA with instructions to publish a legally sufficient final response to the 2007 Petition within 60 days of the issuance of the mandate.”

In implementing the Court’s order within the mandated timeframe, EPA found that it could not make a safety finding to support leaving the current tolerances for residues of chlorpyrifos in place, as required under the FFDCA section 408(b)(2). 21 U.S.C. 346a(b)(2). Under the FFDCA, a tolerance may be left in place only if the Agency determines that the tolerances are safe, *i.e.*, that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residues, including all anticipated dietary exposures and all other exposures for which there is reliable information.” *Id.* Because EPA found that at the time it could not determine that there was a reasonable certainty that no harm would result from aggregate exposure to chlorpyrifos residues, including all anticipated dietary (food and drinking water) exposures and all other exposures, EPA published the final rule revoking all tolerances for chlorpyrifos in the *Federal Register* on August 30, 2021. 86 FR 48315, August 30, 2021 (FRL-5993-04-OCSP) (the Final Rule). As described in greater detail in the Final Rule, the Agency's analysis indicated that aggregate exposures (*i.e.*, exposures from food, drinking water, and residential exposures), which stem from then-currently registered uses, exceeded safe levels. *Id.* at 48317. That analysis relied on the well-established 10% red blood cell acetylcholinesterase (RBC AChE) inhibition level as an endpoint for risk assessment and

included the FFDCA default tenfold (10X) margin of safety to account for uncertainties related to the potential for adverse neurodevelopmental effects to infants, children, and pregnant women. Id. The Final Rule revoked the chlorpyrifos tolerances but provided a transition period of six months, until February 28, 2022. *Id.* at 48334.

Pursuant to FFDCA section 408(g)(2), EPA provided an opportunity to file objections to the Final Rule and seek an evidentiary hearing on those objections. See also 21 U.S.C. 346a(g)(2); 40 CFR 178.32(b). In response to the Final Rule, several objections, hearing requests, and requests to stay the Final Rule were filed by parties representing a wide variety of growers and pesticide users. On February 28, 2022, EPA published its order denying all objections, hearing requests, and requests to stay the Final Rule in the *Federal Register* (87 FR 11222, February 28, 2022) (FRL-5993-05-OCSP) (the Denial Order). EPA's publication of the Denial Order completed the Agency's administrative process for the Final Rule. Pursuant to the terms of the Final Rule, all chlorpyrifos tolerances expired on February 28, 2022. EPA notes that EPA's Final Rule revoking chlorpyrifos tolerances is a separate final agency action, and as such, comments challenging EPA's action in that Final Rule are outside the scope of this Notice. Gharda and several other grower groups have challenged that rule in the U.S. Court of Appeals for the Eighth Circuit, *see Red River Valley Sugarbeet Growers Ass'n et al., v. Regan* (9th Cir. No. 22-1422).

Because at this time there are no tolerances or exemptions from the requirement of a tolerance for chlorpyrifos residues in or on food, there is no basis for allowing food uses to remain on chlorpyrifos registered products. See 21 U.S.C. 346a(a)(1). Therefore, between March 1 and March 9 of 2022, after EPA's publication of the Denial Order, EPA issued letters to all registrants of chlorpyrifos products with food uses confirming revocation of the tolerances and recommending that such registrants consider various cancellation and label amendment options. EPA requested that registrants submit a letter formally expressing their intention to submit registration amendments to remove food uses from product labels or to submit a voluntary

cancellation for products where all uses are subject to the tolerance revocation by March 30, 2022. All chlorpyrifos registrants to whom that letter was sent have submitted requests to voluntarily cancel their pesticide products and/or label amendments to remove food uses from their chlorpyrifos pesticide product labels, with the exception of Gharda, the registrant of products listed in this Notice. While Gharda submitted requests for voluntary cancellation for some uses and some label amendments, that request does not fully align with the revocation of chlorpyrifos tolerances (*i.e.*, it does not result in the removal of all food uses from those registered products); therefore, Gharda's products identified in unit I.A. are subject to this Notice.

IV. Basis for Issuance of Notice of Intent to Cancel

EPA has determined that the chlorpyrifos registrations listed in unit I.A. must be cancelled because they each bear labeling for use on food crops. Due to the lack of tolerances for residues of chlorpyrifos, these products, bearing labeling for use on food crops, (i) pose unreasonable adverse effects on the environment under FIFRA section 2(bb)(2), 7 U.S.C. 136(bb)(2), because use of chlorpyrifos on food results in unsafe pesticide residues under the FFDCA and (ii) are misbranded and thus not in compliance with FIFRA, 7 U.S.C. 136j(a)(1)(E).

As noted in unit II., tolerances establish the maximum amount of pesticide residues that are allowed in or on a food. In situations where no tolerance exists to cover residues of a particular pesticide in or on food, those residues are "deemed unsafe," as a matter of law under the FFDCA. 21 U.S.C. 346a(a)(1). As a consequence, a pesticide resulting in residues in or on food for which there is no tolerance does not meet the FIFRA standard for registration. See 7 U.S.C. 136(bb). Moreover, any food containing "unsafe" pesticide chemical residues is "deemed to be adulterated," and introduction of that food into interstate commerce is a violation of the FFDCA. 21 U.S.C. 342(a)(2)(B), 331(a).

A. The pesticide generally causes unreasonable adverse effects on the environment because it is unsafe as a matter of law.

As discussed in unit II., in order to maintain a registration for a pesticide under FIFRA, a registrant has the burden to demonstrate that the pesticide satisfies the statutory standard for registration. 40 CFR 164.80(b); see also 7 U.S.C. 136a(c)(5). One element of that standard is that the pesticide performs its intended function without unreasonable adverse effects on the environment, which is defined under FIFRA section 2(bb) to include “a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21.” 7 U.S.C. 136(bb). The standard referenced in the FIFRA definition is the FFDCA safety standard, *i.e.*, that tolerances, which cover the amount of pesticide residues in or on food, must be safe. See 21 U.S.C. 346a(b)(2).

Also noted in unit II., it is a matter of law that pesticide chemical residues in or on food are “deemed unsafe,” unless covered by a tolerance or exemption. 21 U.S.C. 346a(a)(1). Any residues from pesticides used on food where no tolerances exist for those residues are, therefore, unsafe. Unsafe residues are not consistent with the FFDCA safety standard. Thus, any pesticide resulting in such residues, causes, as a legal matter, unreasonable adverse effects on the environment. Such pesticide is subject to cancellation under FIFRA section 6(b).

Because all tolerances for chlorpyrifos have been revoked, chlorpyrifos residues in or on food are unsafe as a matter of law. Because the chlorpyrifos registrations listed in unit I.A. bear labeling for use on food, use of which would result in unsafe pesticide residues on food, these products pose unreasonable adverse effects on the environment under FIFRA section 2(bb)(2). 7 U.S.C. 136(bb)(2).

B. The pesticide and its labeling do not comply with FIFRA.

Additionally, because the chlorpyrifos products in unit I.A. bear labeling for use on food, for which the registrant did not submit the necessary label amendments and/or cancellations to remove all food uses, and because all tolerances for chlorpyrifos have been revoked, these products are misbranded and thus not in compliance with FIFRA. It is a violation of FIFRA to sell and distribute pesticides that are misbranded. 7 U.S.C. 136j(a)(1)(E). FIFRA’s definition of

“misbranded” provides many ways in which a pesticide may be misbranded, including if its labeling “bears any statement . . . that is false or misleading.” 7 U.S.C. 136(q)(1)(A). Pesticide labeling bearing directions for use on food crops that results in adulterated food is misleading because it is illegal to distribute that food in commerce. A commercial farmer complying with approved use directions would apply the pesticide to crops but then, in the absence of necessary tolerances or an exemption, would be producing adulterated food, which cannot be delivered into interstate commerce without violating the FFDCA. Thus, the label misleads the consumer into believing a pesticide can be applied to food crops, but ultimately results in adulterated food or feed crops that cannot be sold. To avoid this conflict, EPA’s regulations prevent EPA from issuing a registration for a pesticide that “bears labeling with directions for use on food, animal feed, or food or feed crops, or may reasonable be expected to result, directly or indirectly, in pesticide residues (or results of any active or inert ingredient of the product, or of any metabolite or degradate thereof) in or on food or animal feed,” unless tolerances or exemptions covering such residues have been issued. 40 CFR 152.112(g).

In summary, because the aforementioned products would result in pesticide residues in or on food that are, as a matter of law, unsafe, the products pose unreasonable adverse effects on the environment. Moreover, EPA has determined that because the aforementioned products are misbranded, continued sale and distribution would not comply with the provisions of FIFRA. Consequently, EPA has determined that these products must be cancelled.

V. Status of Products that Become Cancelled

A. Timing of Cancellation

The cancellation of registration for the specific products identified in unit I.A. of this document will be final and effective 30 days after the affected registrant receives notice of EPA’s intent to cancel the pesticide registrations listed in unit I.A., or on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], unless within that time the registrant makes the necessary corrections (see unit V.C.) or a hearing is requested by an

adversely affected person regarding such product. 7 U.S.C. 136d(b).

In the event a hearing is held concerning a particular product, the cancellation of the registration for that product will not become effective except pursuant to (i) an initial decision of the presiding Administrative Law Judge that becomes a final order pursuant to 40 CFR 164.90(b) or (ii) if the Administrative Law Judge's initial decision is appealed or subject to Administrator review pursuant to 40 CFR 164.101, a final order issued by the Environmental Appeals Board or (if the matter is referred to the Administrator pursuant to 40 CFR 164.2(g)) the Administrator. Final cancellation orders following a public hearing are subject to judicial review within 60 days of the entry of the order. 7 U.S.C. 136d(h).

B. Existing Stocks Issues

FIFRA section 6(a)(1) allows the Agency to permit the continued sale and use of existing stocks of pesticides whose use has been cancelled, to the extent the Administrator determines that such sale or use would not be inconsistent with the purposes of this Act. 7 U.S.C. 136d(a)(1). EPA has defined "existing stocks" as "those stocks of a registered pesticide which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action." 56 FR 29362, June 26, 1991 (FRL-3846-4). This section addresses how the Agency intends to treat existing stocks when and if pesticide registrations are cancelled pursuant to this Notice.

The Agency does not believe that continued sale or use of existing stocks of any chlorpyrifos registrations identified in this Notice following cancellation would be consistent with FIFRA. The continued sale and distribution of products cancelled in a proceeding pursuant to this Notice would be the sale and distribution of misbranded products, which, if used in accordance with the labeling, would lead to the production of adulterated food and the use of products that would pose unreasonable adverse effects on human health due to residues in or on food that are inconsistent with the FFDCA safety standard. Accordingly, EPA has determined that the continued sale and distribution of existing stocks of pesticide products cancelled

pursuant to this Notice should not be permitted, with the exception of movement of existing stocks for the sole purposes of lawful export consistent with FIFRA; disposal consistent with applicable state disposal requirements; or return to the registrant consistent with the terms of a return program agreement with EPA, if any. Moreover, EPA does not intend to allow existing stocks in the hands of end-users to continue to be used, unless they are being used for non-food uses. Any use of chlorpyrifos on food would result in adulterated food, which is illegal to deliver into interstate commerce; therefore, use of existing stocks for use on food cannot be permitted.

It is settled law that existing stocks issues are not required to be a part of a cancellation proceeding, and that the treatment of existing stocks issues is only included as an issue in a cancellation proceeding when the Notice giving rise to the right to a hearing voluntarily identifies and includes existing stocks as an issue for examination. See *In the Matter of Cedar Chemical Co., et al.*, 2 E.A.D. 584, nn. 7, 9, 1988 WL 525242 (June 9, 1988) (Decision of the Administrator). The Administrator's decision in *Cedar Chemical* on whether existing stocks had to be included as an issue in the hearing was affirmed by the United States Court of Appeals for the Ninth Circuit in *Northwest Food Processors Association v. Reilly*, 886 F. 2d 1075, 1078 (9th Cir. 1989). In the case of this Notice, EPA has determined not to include existing stocks as an issue in any hearing arising from this Notice, since the lack of tolerances means that any continued sale, distribution, or use of the pesticide would be inconsistent with the purposes of FIFRA. Instead, the only issue for hearing under this Notice is whether the subject products should be cancelled.

C. Potential Scope of Final Action

FIFRA section 6(b) allows the registrant, within the 30 days following publication or receipt of EPA's notice, to "make the necessary corrections, if possible". 7 U.S.C. 136d(b). As noted in unit IV., the chlorpyrifos products listed in unit I.A. must be cancelled because they bear labeling for use on food although no tolerances exist to cover chlorpyrifos residues in or on food for those uses. Terminating food uses and removing those uses from labels would resolve the

violations EPA has identified in this Notice. Therefore, EPA recognizes that the registrant has an opportunity to make corrections by requesting cancellation of these uses and amending labels.

FIFRA section 6(b) also states “in taking any final action under this subsection, the Administrator shall consider restricting a pesticide’s use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the *Federal Register* an analysis of such impact.” Id.

Accordingly, in any final action on this Notice, EPA may consider, as an alternative to cancellation of the whole registrations, cancelling only those uses that result in residues in or on food. As part of its registration review of chlorpyrifos, EPA considered the potential economic impacts on growers if chlorpyrifos use was eliminated for various registered food crops. *See* Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101) (November 18, 2020), available at <https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969>; Chlorpyrifos Revocation Small Business and Employment Analysis (August 12, 2021), available at <https://www.regulations.gov/document/EPA-HQ-OPP-2021-0523-0031>. Although EPA may consider benefits for certain uses under FIFRA, economic impacts to growers is not a consideration for EPA in making a safety determination under the FFDCA. Because EPA determined that the tolerances did not meet the safety standard under the FFDCA, EPA revoked all chlorpyrifos tolerances. See 86 FR 48315. As a result, chlorpyrifos may not be used in or on food without resulting in adulterated food, which cannot be distributed in interstate commerce. Restricting the chlorpyrifos products listed in unit I.A. to only those uses that do not result in residues in or on food would have no economic impact, beyond the impact already resulting from the revocation of the chlorpyrifos tolerances, since these products already cannot be used on food due to the lack of tolerances.

VI. Mandated FIFRA Reviews

A. What is required?

When EPA intends to issue a NOIC, it must furnish a draft of that Notice and an analysis of the impact of the proposed action on the agricultural economy to the Secretary of the USDA for comment at least 60 days prior to sending such Notice to the registrant or making such Notice public. 7 U.S.C. 136d(b). When a public health use is affected, FIFRA section 6(b) also directs the Secretary of the Department of Health and Human Services (HHS) to provide available benefits and use information, or an analysis thereof. Within the same time period, the Agency must also submit the proposed cancellation action to the FIFRA Scientific Advisory Panel (SAP) for comment concerning the impact of the proposed action on health and the environment, unless the SAP agrees to waive its review. 7 U.S.C. 136w(d).

In the event that written comments are received from the USDA, HHS, or the SAP within 30 days of such referral, the Agency must publish those comments and the Agency's response to the comments.

B. What are the results of this review?

Because all tolerances for chlorpyrifos have already been revoked for the reasons set forth in the Final Rule and Denial Order, this proposed cancellation action itself is not anticipated to have any impacts on the agricultural economy. This NOIC is purely an administrative action to address three registrations that the registrant is unable or unwilling to cancel or modify to comply with the Agency's tolerance revocation. EPA provided a draft of this NOIC to the SAP requesting a waiver due to the lack of scientific issues for consideration by the SAP. The SAP waived its review of this NOIC on August 19, 2022.

This NOIC is not subject to review by HHS because there are no public health uses affected by this NOIC.

On August 11, 2022, EPA provided a draft of this NOIC to USDA for review and received a response from USDA on September 11, 2022. USDA expressed three major concerns in its comments: (1) that an economic analysis was not provided for review in conjunction with

the draft NOIC; (2) USDA's opinion that historical precedent and procedures was not followed; and (3) USDA's opinion that EPA could have retained some tolerances consistent with the proposal in the Proposed Interim Registration Review Decision for Chlorpyrifos (2020 PID) instead of revoking all tolerances and should initiate action to reestablish tolerances consistent with the conclusions of the 2020 PID. USDA's comments are available at <https://www.regulations.gov> in the docket for this action, docket ID EPA-HQ-OPP-2022-0417.

The Agency has considered each of these comments prior to finalizing this Notice. Below is a summary of these comments and the Agency's detailed responses to these comments.

Comment: USDA notes that FIFRA requires EPA to consider the impact of the action proposed in the NOIC on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy and to provide that analysis to the USDA. USDA expressed concern with statements in EPA's draft NOIC that the cancellation of the products would produce no negative effects beyond those that were already imposed when EPA revoked the chlorpyrifos tolerances. Since, as USDA notes in their comments, the FFDCA does not provide for consideration of economic impacts in a determination of whether to retain tolerances, the USDA had concerns about the lack of consideration to the economy.

EPA Response: As noted in unit III, EPA revoked the chlorpyrifos tolerances in a final rule issued in August 2021, as a result of concluding that the chlorpyrifos tolerances were not safe. As USDA recognizes, the FFDCA does not authorize EPA to consider economic impacts to farmers when determining whether to retain tolerances. As noted in the Final Rule and the Denial Order, the FFDCA permits EPA to leave a tolerance in place only if it is safe; whether a tolerance is important to the agricultural economy is not a permissible consideration for EPA in determining whether to leave a tolerance in place.

When the tolerances were revoked, chlorpyrifos was no longer permitted to be used on food crops. Although not a consideration under the FFDCA, as part of its assessment of chlorpyrifos in registration review, EPA prepared a benefits assessment and a small business

analysis of the economic benefits of chlorpyrifos for a variety of crops as well as the potential economic impact if chlorpyrifos were not available. *See Revised Benefits of Agricultural Uses of Chlorpyrifos* (PC# 059101) (November 18, 2020), available at <https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969>; *Chlorpyrifos Revocation Small Business and Employment Analysis* (August 12, 2021), available at <https://www.regulations.gov/document/EPA-HQ-OPP-2021-0523-0031>.

Although the benefits assessment and small business analysis did indicate some economic impacts as a result of chlorpyrifos not being available for growers, those impacts have already occurred as a result of the revocation of the tolerances and would not be attributable to the cancellation of these products. Even if these products were not cancelled, the products could still not be used as a result of the tolerance revocation; thus, the same economic impact would result with or without this cancellation action. To the extent the products being cancelled are registered for non-food uses, these are not the only chlorpyrifos products registered for these non-food uses. Consequently, EPA concluded that the cancellation action being proposed in this NOIC itself does not actually result in any impact on agricultural commodities, retail food prices, or the agricultural economy.

Comment: USDA notes that it considers EPA's process for revoking tolerances as "harmful precedent" that has created confusion and concern among agricultural stakeholders and international trading partners. USDA asserts that the lack of a phase-out period has caused a widespread disposal problem for existing stocks of chlorpyrifos, and that the "divergence from normal procedures caused confusion and concerns" and may "harm the economic viability of U.S. producers in the long-term" by undercutting U.S. credibility in future trade negotiations.

EPA Response: As an initial matter, EPA notes that this comment does not appear to be directly relevant to the cancellation of the particular products identified in this NOIC, but rather a commentary on EPA's issuance and implementation of the final rule revoking tolerances. Prior to the issuance of the final rule, EPA coordinated with FDA and USDA to ensure they could

develop any necessary enforcement guidance, such as how long legally treated food and feed commodities may be in the channels of trade, and FDA released a document entitled *Guidance for Industry: Questions and Answers Regarding Channels of Trade Policy for Human Food Commodities with Chlorpyrifos Residues*, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-channels-trade-policy-human-food-commodities>, in order to provide guidance to stakeholders in the food industry. In addition, in the Final Rule itself and contrary to the USDA's assertion, EPA did provide a six-month transition period between the publication of the final revoking tolerances and the effective date of the revocation consistent with the Agency's obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures. Although EPA recognizes that there has been confusion in the regulated community on what to do with registered chlorpyrifos products that can no longer be used on food, EPA is, and has been, working with registrants to provide for an appropriate transition. Specifically, the Agency continues to work with the registrants in the development of their return programs and update stakeholders and the Agency's website with the latest information regarding chlorpyrifos.

To the extent this comment expressed a concern about the process EPA used for terminating use of chlorpyrifos on food, EPA fully addressed this comment in its Denial Order. *See* 87 FR at 11247-49. Objectors to EPA's Final Rule alleged that EPA was required to negotiate with chlorpyrifos registrants and cancel food uses under FIFRA before revoking tolerances under the FFDCA. Consistent with EPA's position in the Denial Order, neither FIFRA nor the FFDCA direct that the Agency proceed with cancellation under FIFRA prior to revoking tolerances under the FFDCA. *Id.* Where EPA determines that tolerances are not safe, the FFDCA requires that tolerances be revoked, regardless of the economic impact of that revocation. In addition, in this particular instance, the Ninth Circuit prioritized the Agency taking action under the FFDCA over taking action under FIFRA, by ordering EPA to take action on the tolerances within 60 days of the issuance of the mandate in that case, *i.e.*, August 20, 2021, and to take

action to cancel food uses “in a timely fashion”. *LULAC*, 996 F.3d. at 703-04.

Nonetheless, even with the restricted timeframe imposed by the Ninth Circuit and the need to prioritize tolerance actions under the FFDCA over cancellations under FIFRA, EPA did attempt to coordinate the tolerance revocations with cancellation actions. While EPA was unable to complete the necessary steps for that process to impact the tolerance revocation rule for chlorpyrifos by the Court’s deadline, EPA recognizes that coordinating tolerance revocations and FIFRA cancellations can be helpful since product cancellation orders can provide clarity around existing stocks and disposal procedures.

Comment: USDA’s comments outline its opinion that the Agency could have pursued a pathway on the 11 high benefit uses outlined in the 2020 PID instead of revoking all tolerances. USDA also requests Agency-initiated action to reestablish tolerances consistent with the conclusions of the 2020 PID.

EPA Response: EPA notes that this comment appears to be more appropriately directed towards the Final Rule itself rather than the cancellation action that is the subject of this NOIC. Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of the 2021 final tolerance rule and may also request a hearing on those objections. USDA did not file any such objection, although several other parties did, asserting that EPA should have left tolerances in place associated with 11 uses as described in the 2020 PID rather than revoking all the tolerances. EPA denied that objection in its Denial Order. See 87 FR at 11244-47. The Denial Order fully explained the rationale for not adopting the proposal presented in the 2020 PID. Briefly, in the December 2020 PID, EPA proposed that all chlorpyrifos uses contributing aggregate exposures be cancelled except for 11 specific uses in specific geographic areas. Those 11 uses were identified by registrants and EPA as having high benefits, although the Agency recognized that it was just one possible subset of uses that might be retainable. The Agency’s proposed safety determination for those uses was contingent on other uses being cancelled and additional use restrictions being in effect. It is also important to note that the findings in the PID

were simply proposals, and those proposals, and the underlying risk assessments on which those proposals were based, were subject to public comment and did not represent a final safety determination. Despite the potential for supporting a safety finding consistent with the PID, at the time that EPA was required to expeditiously issue a rule by the Ninth Circuit, no concrete steps had been taken by registrants under FIFRA to implement the PID proposal: no uses had been cancelled, no labels had been revised to geographically limit applications or limit maximum application rates, nor had any applications to initiate such actions been filed with the Agency. Therefore, at the time of the Final Rule, the option to leave certain tolerances in place was not available. Thus, EPA assessed aggregate exposure based on all currently registered uses of chlorpyrifos as required by the FFDCA and consistent with its guidance, finding that it could not determine that there was a reasonable certainty of no harm from aggregate exposure. As a result, chlorpyrifos tolerances were revoked and expired as of February 28, 2022.

A challenge to the Final Rule is outside the scope of this NOIC. All the chlorpyrifos tolerances have been revoked, so the products identified in this document must be cancelled because they bear labeling for use on food. As noted above, the Agency views this NOIC as an administrative action, as once tolerances were revoked, chlorpyrifos products cannot bear labeling for use on food, since the products could no longer be used without rendering food and feed crops adulterated.

The request to reestablish tolerances associated with those 11 uses is also outside the scope of this NOIC. At this time, the Agency does not intend to initiate a rulemaking to reestablish those tolerances. Initiating tolerance rulemaking under section 408(e) of the FFDCA is a discretionary action, 21 U.S.C. 346a(e), and at this time, no petition has been submitted requesting specific tolerances to be established under section 408(d) of the FFDCA, 21 U.S.C. 346a(d). Even if EPA initiated such a rulemaking, or if a petition were submitted, EPA would need to follow the statutory process and make a determination that the tolerances were safe in order to establish them. It is important to note that the proposal in the 2020 PID was only a

proposed safety finding based on a subset of uses; it was not a final determination of safety. Any final safety determination supporting the re-establishment of the tolerances would need to take into consideration aggregate exposures to chlorpyrifos.

VII. Requesting a Hearing

This unit explains how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing.

A. Who can request a hearing?

A registrant or any other person who is adversely affected by a cancellation of registration as described in this Notice may request a hearing.

B. When must a hearing be requested?

A request for a hearing by a registrant must be submitted in writing within 30 days after the date of receipt of the NOIC, or within 30 days after publication of this announcement in the *Federal Register*, whichever occurs later. A request for a hearing by any other person adversely affected by the Agency's proposed action must be submitted within 30 days after the date of publication of this Notice in the *Federal Register*. See the **DATES** section of this document.

C. How must a hearing be requested?

All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings, 40 CFR part 164. Among other requirements, these rules include the following requirements:

- Each hearing request must specifically identify by registration or accession number each individual pesticide product for which a hearing is requested, 40 CFR 164.22(a);
- Each hearing request must be accompanied by a document setting forth specific objections that respond to the Agency's reasons for proposing cancellation as set forth in this Notice, and stating the factual basis for each such objection, 40 CFR 164.22(a); and
- Each hearing request must be received by the OALJ within the applicable 30-day period, 40 CFR 164.5(a).

Failure to comply with any one of these requirements will invalidate the request for a hearing and, in the absence of a valid hearing request, result in final cancellation for the products in question by operation of law.

D. Where does a person submit a hearing request?

Requests for hearing must be submitted to the OALJ. The OALJ strongly encourages electronic filing due to the coronavirus pandemic. *See* Order Urging Electronic Service and Filing, issued by Chief ALJ Biro (April 10, 2020), available at https://www.epa.gov/sites/default/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf.

1. *Submitting the hearing request electronically.* To file a document electronically, a party shall use a web-based tool known as the OALJ E-Filing System by visiting the OALJ's website at <https://www.epa.gov/alj>. Documents filed electronically are deemed to constitute both the original and one copy of the document.

Any party choosing to file electronically must first register with the OALJ E-Filing System at https://yosemite.epa.gov/oa/eab/EAB-ALJ_Upload.nsf. There may be a delay of one to two business days between the time a party applies for registration and the time at which the party is able to upload documents into the system.

A document submitted to the OALJ E-Filing System is considered "filed" at the time and date of electronic reception, as recorded by the OALJ E-Filing System immediately upon reception. To be considered timely, documents submitted through the OALJ E-Filing System must be received by 11:59 p.m. Eastern Time on the date the document is due, unless another time is specified by the Judge. Within an hour of a document being electronically filed, the OALJ E-Filing System will generate an electronic receipt of the submission that will be sent by email to both the party submitting the document and the Headquarters Hearing Clerk. This emailed electronic receipt will be the filing party's only proof that the OALJ received the submitted document. The absence or presence of a document on the OALJ's E-Docket Database

webpage, available at https://yosemite.epa.gov/oarm/alj/alj_web_docket.nsf, or on the Agency's Administrative Enforcement Dockets webpage, available at <https://yosemite.epa.gov/oa/rhc/epaadmin.nsf>, is not proof that the document was or was not received. If the filing party does not receive an electronic receipt within one hour after submitting the document through the OALJ E-Filing System, the Headquarters Hearing Clerk may be able to confirm receipt of the document but not earlier than one hour after the document was submitted.

The OALJ E-Filing System will accept any type of digital file, but the file size is limited to 70 megabytes. Electronically filed textual documents must be in Portable Document Format ("PDF"). If a party's multimedia file exceeds 70 megabytes, the party may save the file on a compact disc and send it by U.S. mail to the Hearing Clerk mailing address identified in unit VII.D.2. of this Notice, or the party may contact the Headquarters Hearing Clerk at (202) 564-6281 for instructions on alternative electronic filing methods.

A motion and any associated brief may be filed together through the OALJ E-Filing System. However, any documents filed in support of a brief, motion, or other filing, such as copies of proposed exhibits submitted as part of party's prehearing exchange, should be filed separately as an attachment. Where a party wishes to file multiple documents in support of a brief, motion, or other filing, rather than filing a separate attachment for each such document, the documents should be compiled into a single electronic file and filed as a single attachment, to the extent technically practicable.

2. *Submitting the hearing request by non-electronic means.* Alternatively, if a party is unable to file a document utilizing the OALJ E-Filing System, *e.g.*, the party lacks access to a computer, the party may file the document by U.S. mail or facsimile, although the OALJ's ability to receive filings via those methods is limited. U.S. mail is currently being delivered to the OALJ at an offsite location on a weekly basis only, and documents sent by facsimile will also be received offsite. If a party must file documents by U.S. mail or facsimile, the party shall

notify the Headquarters Hearing Clerk each time it files a document in such a manner by calling (202) 564-6281.

To file a document using U.S. mail, the document shall be sent to the following mailing address: Mary Angeles, Headquarters Hearing Clerk, Office of Administrative Law Judges (Mail Code 1900R), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

Please note that mail deliveries to federal agencies are screened off-site, and this security procedure can delay delivery.

Facsimile may be used to file a document if it is fewer than 20 pages in length. To file a document using facsimile, the document shall be sent to OALJ's offsite location at (916) 550-9639.

A document submitted by U.S. mail or facsimile is considered "filed" when the Headquarters Hearing Clerk physically receives it, as reflected by the inked date stamp physically applied by the Headquarters Hearing Clerk to the paper copy of the document.

At this time, the OALJ is not able to accept filings or correspondence by courier or commercial delivery service, such as UPS, FedEx, and DHL. Likewise, the physical office of the OALJ is not currently accessible to the public, and the OALJ is not able to receive documents by personal delivery. For further information on filings with the OALJ, please see <https://www.epa.gov/alj>.

3. *Important reminders.* Regardless of the method of filing, all filed documents must be signed in accordance with 40 CFR part 164 and must contain the contact name, telephone number, mailing address, and email address of the filing party or its authorize representative. A copy of each document filed in this proceeding shall also be "served" by the filing party on the presiding judge and on all other parties.

E. The Hearing.

If a hearing concerning any product affected by this Notice is requested in a timely and

effective manner, the hearing will be governed by the Agency's Rules of Practice Governing Hearings, 40 CFR part 164, and the procedures set forth in this unit. Any interested person may participate in the hearing, in accordance with 40 CFR 164.31.

F. Separation of Functions.

EPA's Rules of Practice forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding *ex parte* with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives. 40 CFR 164.7. To facilitate compliance with the *ex parte* rule, the following are designated as adjudicatory personnel for purposes of this proceeding: the Administrative Law Judges and their staff and the Environmental Appeals Board and its staff. None of the persons identified as adjudicatory personnel may discuss the merits of the proceeding with any person with an interest in the proceeding, or representative of such person, except in compliance with 40 CFR 164.7.

List of Subjects

Environmental protection, Pesticides and pests, Cancellation.

Dated: December 9, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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